Reply Brief

Applicant(s)	Turner et al.
Application #	09/918,359
Date Filed	July 30, 2001
Title	Human Ion Channel Proteins and Polynucleotides Encoding the Same (As Previously Amended)
Attorney Docket #	LEX-0208-USA
Group Art Unit	1646
Examiner	J. Murphy

1 of 3

Filed in Triplicate

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Turner Jr. *et al.* (As Previously Amended)

Serial No.:	09/918,359	Group Art Unit:	1646
Filed:	07/30/2001	Examiner:	J. Murphy

For: Human Ion Channel Proteins and Polynucleotides Encoding the Same (As Previously Amended)

Attorney Docket No.: LEX-0208-USA

REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

REPLY BRIEF

Sir:

Appellants hereby submit an original and two copies of this Reply Brief to the Board of Patent Appeals and Interferences ("the Board") in response to the Examiner's Answer mailed on March 4, 2004. The Reply Brief is due on May 4, 2004. This Reply Brief is therefore timely submitted, and Appellants believe no fees are due in connection with this Reply Brief. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason related to this communication, the Commissioner is authorized to charge any underpayment or credit any overpayment to Lexicon Genetics Incorporated Deposit Account No. 50-0892.

I. REAL PARTY IN INTEREST

Appellants agree with the Examiner's assertion that "(a) statement identifying the real party in interest is contained in the brief" (Examiner's Answer at page 2).

II. RELATED APPEALS AND INTERFERENCES

Appellants agree with the Examiner's assertion that "(a) statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief" (Examiner's Answer at page 2).

III. STATUS OF THE CLAIMS

Appellants agree with the Examiner's assertion that "(t)he statement of the status of the claims contained in the brief is correct" (Examiner's Answer at page 2).

IV. STATUS OF THE AMENDMENTS

Appellants agree with the Examiner's assertion that "(n)o amendment after final has been filed" (Examiner's Answer at page 2).

V. SUMMARY OF THE INVENTION

Appellants disagree with the Examiner's assertion that "(t)he summary of invention contained in the brief is essentially correct" (Examiner's Answer at page 2), allegedly because "the asserted utilities for the claimed invention are in dispute" (Examiner's Answer at page 2). Appellants submit that the summary of **the invention** includes aspects of **the invention** that are described in the specification as originally filed, and are thus properly included in this section of the Appeal Brief. That the Examiner disagrees with Appellants' assertions concerning the **utility** of the present invention is blatantly obvious, given the fact that an Appeal Brief needed to be filed in the first place, but this does not mean that the summary of **the invention** as set forth by Appellants in the Appeal Brief is only "essentially correct".

VI. ISSUES ON APPEAL

Appellants agree with the Examiner's assertion that "(t)he appellant's (*sic*) statement of the issues in the brief is correct" (Examiner's Answer at page 2).

VII. GROUPING OF THE CLAIMS

Appellants agree with the Examiner's assertion that "Appellant's (*sic*) brief includes a statement that the claims stand or fall together" (Examiner's Answer at page 2).

VIII. CLAIMS APPEALED

Appellants agree with the Examiner's assertion that "(t)he copy of the appealed claims contained in the Appendix to the brief is correct" (Examiner's Answer at page 2).

IX. PRIOR ART OF RECORD

Appellants note for the record that **only** the first three references listed by the Examiner (Doerks *et al.*, *Trends in Genetics* **14**:248-250, 1998; Bork *et al.*, *Trends in Genetics* **12**:425-427, 1996; Brenner *et al.*, *Trends in Genetics 15*:132-133, 1999; Examiner's Answer bridging pages 2 and 3) are "relied on" (MPEP Section 1208) by the Examiner in the rejections of the claims that form the basis

for the present appeal, and that the other two references listed by the Examiner (Voet *et al.*, *Biochemistry*, John Wiley & Sons, Inc., pp. 126-128 and 228-234; Adams *et al.*, GenBank Accession Number AA309878; Examiner's Answer at page 3) were "relied on" by the Examiner in rejections that have been overcome by Appellants, and are therefore **not** a part of the present appeal.

X. ARGUMENT

A. Do Claims 1 and 5-9 Lack a Patentable Utility?

Appellants do not wish to restate all of the arguments presented in the Appeal Brief concerning the Examiner's allegation that claims 1 and 5-9 lack a patentable utility, and instead incorporate the entirety of Section VIII(A) of the Appeal Brief at this point herein by reference. However, Appellants are compelled to specifically address certain arguments presented in the Examiner's Answer for the record.

Appellants pointed out both in the Appeal Brief that the present nucleic acid sequences have utility in diagnostic assays, such as forensic analysis, as described in the specification as originally filed (see, for example, page 10, lines 27-33). As described in the specification from page 15, line 33 through page 16, line 32, the presently claimed sequence defines a number of coding single nucleotide polymorphisms - specifically, an A/G transition at nucleotide position 271 of SEQ ID NO:6, which can result in an asparagine or glutamate being present at corresponding amino acid position 91 of SEQ ID NO:7; a C/G transversion at nucleotide position 364 of SEQ ID NO:6, which can result in an arginine or glycine being present at corresponding amino acid position 122 of SEQ ID NO:7; a G/A transition at nucleotide position 367 of SEQ ID NO:6, which can result in a glycine or serine being present at corresponding amino acid position 123 of SEQ ID NO:7; a T/A transversion at nucleotide position 699 of SEQ ID NO:6, which can result in a serine or asparagine being present at corresponding amino acid position 233 of SEQ ID NO:7; a T/C transition at nucleotide position 1013 of SEQ ID NO:6, which can result in an isoleucine or threonine being present at corresponding amino acid position 338 of SEQ ID NO:7; a G/A transition at nucleotide position 1015 of SEQ ID NO:6, which can result in an valine or methionine being present at corresponding amino acid position 339 of SEQ ID NO:7; a C/A transversion at nucleotide position 1397 of SEQ ID NO:6, which can result in a proline or histidine being present at corresponding amino acid position 466 of

SEQ ID NO:7; a G/C transversion at nucleotide position1405 of SEQ ID NO:6, which can result in an aspartate or histidine being present at corresponding amino acid position 469 of SEQ ID NO:7; and a G/T transition at nucleotide position 1419 of SEQ ID NO:6, which can result in a glutamate or aspartate being present at corresponding amino acid position 473 of SEQ ID NO:7. Appellants pointed out that as such polymorphisms are the basis for **forensic** analysis, which does not require any information at all about the ultimate biological function of the encoded protein, and that is undoubtedly a "real world" utility, the presently claimed sequence must in itself be useful.

Appellants first wish to clarify a mischaracterization of statements made by Appellants in the Appeal Brief. The Examiner states that "Appellant further argues that the disclosed polymorphisms are useful to distinguish 50% of the population, because it is an inherent property of any polymorphic marker to distinguish 50% of the population" (the Examiner's Answer at page 6). What Appellants **actually** said in the Appeal Brief was that "in the worst case scenario, the described polymorphisms are each useful to distinguish 50% of the population (in other words, the marker being present in half of the population)" and "that the ability of a polymorphic marker to distinguish at least 50% of the population is an inherent feature of any polymorphic marker" (Appeal Brief at page 6). Thus, it is Appellants' position that any polymorphic marker is useful to distinguish **at least** 50% of the population, not exactly 50% of the population. The largest percentage of a population that two polymorphic markers can define is 50% each, and thus this is the least informative marker, *i.e.*, the **worst case** scenario. If one marker is present at a level of less than 50%, then that marker is even **more** informative, *i.e.*, a **greater** percentage of the population can be distinguished on the basis of the marker. Nevertheless, as pointed out by Appellants, the ability to eliminate **at least** 50% of the population from a forensic analysis clearly is a real world, practical utility.

The Examiner admits that "(t)his asserted utility is credible, but not specific or substantial", because "the specification does not disclose the nexus between any of these polymorphisms and any function of the expressed polypeptide", and "(a)dditionally, there is no correlation disclosed between the presence of any of these polymorphisms and the effect of the presence of any of these polymorphisms on the risk of any disease or condition" (the Examiner's Answer at page 6). Appellants respectfully point out that there are **many** uses of the presently identified polymorphisms in forensic analysis that do **not** require a "nexus

between any of these polymorphisms and any function of the expressed polypeptide", or a correlation "between the presence of any of these polymorphisms and the effect of the presence of any of these polymorphisms on the risk of any disease or condition", specifically, the use of forensic analysis to distinguish **an individual** from **other individuals**, based solely on the **presence** or **absence** of the described polymorphism. Appellants respectfully point out that this is one way in which polymorphic markers such as the presently described polymorphisms have been used for decades in forensic analysis. Therefore, this is clearly a well established technique, and as such, specific guidance does not need to be provided in the present specification, for it has long been established that a patent need not disclose what is well known in the art (*In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988)). Thus, the Examiner's argument does not support the allegation that the presently claimed invention lacks a patentable utility.

The Examiner next states that "(s)ignificant further experimentation would be required of the skilled artisan to identify individuals with a disease or disorder which (*sic*) correlates to the presence of one of the enumerated polymorphisms, therefore, since this asserted utility is not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial" (the Examiner's Answer at page 7). Appellants hardly know where to begin. Naturally occurring genetic polymorphisms such as those described in the specification as originally filed are both the basis of, and critical to, *inter alia*, forensic genetic analysis intended to resolve issues of, for example, identity or paternity. Forensic analysis based on polymorphisms such as those identified by Appellants is used to positively identify or rule out suspects in many criminal cases, and in identifying human remains. Paternity determination is based on polymorphisms such as those identified by Appellants to positively identify or rule out individuals suspected of fathering a particular child. Therefore, Appellants find the Examiner's position particularly difficult to comprehend. What could be possibly be more substantial and real world than the loss of an individual's freedom or life through incarceration? What could be possibly be more substantial and real world than the positive identification of human remains? What could be possibly be more substantial and real world than the impact, both economic and emotional, that the results of a paternity analysis has on the individuals directly and indirectly involved? These are all well known and generally accepted uses of polymorphisms such as the polymorphisms identified by Appellants. Without such identified polymorphisms, the skilled

artisan would not be able to carry out such forensic or paternal analyses. Thus, the Examiner's allegations that the presently described polymorphisms are not "mature" and could not be "readily used in a real world sense" are completely without merit, and in no way whatsoever support the allegation that the presently claimed sequence lacks a patentable utility.

The Examiner further questions this asserted utility, stating "(s)uch assays can be performed with any polynucleotide" (the Examiner's Answer at page 7). Appellants reiterate that this argument is flawed in a **number** of respects. First, this allegation is directly contradicted by the **Examiner himself**, who in just the second sentence after this allegation, states that "polymorphisms exist in **many** genes, and could be use (*sic*) for forensic analysis" (the Examiner's Answer at page 7, emphasis added). Thus, even the Examiner does not believe that "(s)uch assays can be performed with **any** polynucleotide" (emphasis added). Second, Appellants submit that the asserted forensic utility is specific precisely because it cannot be applied to just any polynucleotide. In fact, the basis for forensic analysis is the fact that such polymorphic markers are **not** present in all other nucleic acids, but in fact specific and unique to only a certain subset of the population. Third, until a polymorphic marker is actually described it cannot be used in forensic analysis. Put another way, simply because there is a likelihood, even a significant likelihood, that a particular nucleic acid sequence will contain a polymorphism and thus be useful in forensic analysis, until such a polymorphism is actually identified and described, such a likelihood is **meaningless**. The Examiner appears to be attempting to use the information presented for the first time by Appellants in the instant specification as hindsight verification that the presently claimed sequence would be expected to have polymorphic markers. Such hindsight analysis based on Appellants discovery is completely improper. Fourth, the Examiner is clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. The fact that other polymorphic markers have been identified in other genetic loci does not mean that use of the polymorphic markers identified by Appellants' in SEQ ID NO:6 in forensic analysis is not a specific utility. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has

> only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Following directly from the quote above, an invention does not need to be the **only way** to accomplish a certain result. Thus, the question of whether or not other nucleic acid sequences contain polymorphic markers and can thus be used in forensic analysis is **completely irrelevant** to the present utility inquiry. The **only** relevant question in regard to meeting the standards of 35 U.S.C. § 101 is whether **every** nucleic acid can be so used - and the clear answer to this question is an emphatic **no**. Importantly, the holding in the *Carl Zeiss* case is **mandatory legal authority** that essentially controls the outcome of the present case. This case, and particularly the cited quote, **directly** rebuts the Examiner's argument.

The Examiner states that "(t)he use of the claimed nucleic acid in forensic analysis is not particular to the sequence being claimed because it would be applicable to the general class of nucleic acids" (the Examiner's Answer at page 7). Appellants will attempt a remedial explanation in order to clear up the Examiner's misconceptions regarding forensic analysis and the utility standard under 35 U.S.C. § 101. The "general class" to which the Examiner refers is **all** nucleic acids. Appellants reiterate that **not all nucleic acids contain polymorphisms**. Therefore, the question of whether the asserted utility is "particular to the sequence being claimed" instead of a general utility that "would be applicable to the general class of nucleic acids" has **clearly** been laid to rest. The Examiner **repeatedly**, throughout the Examiner's Answer, alleges that he is not confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, but then consistently attempts to **narrowly** define the "general class" of the invention to include **only** those members that share the asserted utility, and then state that the asserted utility is "applicable to the general class of nucleic acids". Appellants respectfully point out that the "general class of nucleic acids" **cannot** be redefined to include **only** those nucleic acids that contain polymorphic markers, as the Examiner is forced to do in order to support the allegation that the claimed nucleic acids lack a patentable utility. Therefore the present claims are clearly in compliance with 35 U.S.C. § 101.

In the Examiner's Answer, the Examiner once again attempts to distinguish the holding in *Carl Zeiss* from the present case, stating that "Carl Zeiss is inapposite to the facts of the instant case" because "(i)n

the instant case, however, the claims lack utility not because they are incomplete, and not because they do not set forth the best or only way to accomplish a result, and not because they are not unique, but because they do not have either a well-established utility or a specific and substantial asserted utility" (the Examiner's Answer bridging pages 7 and 8). Appellants have detailed the many shortcomings of this argument above, and respectfully reiterate that many aspects of **forensic** analysis does not require **any** knowledge about "any function of the expressed polynucleotide" or a correlation "between the presence of any of these polymorphisms and the effect of the presence of any of these polymorphisms on the risk of any disease or disorder". Forensic analysis is used to distinguish individual members of the human population from one another based simply on the presence or absence of one or more of the described polymorphisms. No more and no less is required. **No** knowledge about the function of the encoded protein is required. **No** nexus between the polymorphic markers and a specific disease or disorder is required. The present polymorphic markers clearly have utility in forensic analysis, and, thus, the claims meet the requirements of 35 U.S.C. § 101.

Furthermore, Appellants note that the Examiner repeatedly cites the need for "further experimentation" (the Examiner's Answer at pages 7, 9, and 13), "additional experimentation" (the Examiner's Answer at page 8), or "further research" (the Examiner's Answer at pages 9 and 15) throughout the Examiner's Answer to support the allegation that the present invention lacks a patentable utility. Appellants reiterate that the standard for meeting the requirements of 35 U.S.C. § 101 is not whether "further experimentation", "additional experimentation", or "further research" is required to practice certain aspects of the claimed invention, but whether **undue** experimentation would be required to practice the claimed invention. The widespread use of polymorphisms such as those described by Appellants in forensic analysis every day **strongly** argues against such a use requiring "undue experimentation". In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v.*

Chugai Pharmaceutical Co., Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands, supra.* Thus, the Examiner's argument does not support the alleged lack of utility, and the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner then states that "the alleged utility of the nucleic acid in an (*sic*) method of forensic analysis would not provide a utility for nucleic acids encoding a protein or the protein encoded thereby" (the Examiner's Answer at page 9). This statement could not be further from the truth. Appellants respectfully point out that the described polymorphisms are **included** in the claimed nucleic acid sequence, and thus **one** of the utilities of the claimed nucleotide sequence is to use the described polymorphisms in forensic analysis, as described in detail, above. Appellants reiterate that only one credible assertion of utility is needed in order to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)). Thus, **none** of the Examiner's arguments concerning the use of the described polymorphism in forensic analysis support the alleged lack of utility. Therefore, the present claims clearly meet all standards for patentability under 35 U.S.C. § 101.

Appellants point out for the record that the Examiner has provided absolutely **no** evidence of record that would serve to show that an artisan skilled in the art of forensic analysis would doubt Appellants asserted utility. As set forth by Appellants in the Appeal Brief, it has been clearly established that a statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA, 1974; "*Langer*"); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA, 1971). As set forth in *In re Langer* (183 USPQ 288 (CCPA 1974); "*Langer*"):

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence

sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, absent such **evidence** from the Examiner concerning the use of the presently described polymorphisms in forensic analysis, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Additionally, in the Appeal Brief, Appellants pointed out that a sequence sharing nearly 100% percent identity at the protein level over extended portions of the claimed sequence is present in the leading scientific repository for biological sequence data (GenBank), and had been annotated by third party scientists *wholly unaffiliated with Appellants* as "Homo sapiens two-pore calcium channel protein 2". As set forth repeatedly by Appellants, the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. Given this GenBank annotation, there can be no question that those skilled in the art would clearly believe that Appellants' sequence is an ion channel protein, exactly as asserted by Appellants in the specification as originally filed (at least at page 2, lines 5-7). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner once again questions this asserted utility, stating that "the art recognizes the assignment of function based on homology is inherently difficult, as evidenced by the references of Doerks [Doerks *et al.*, *Trends in Genetics* **14**:248-250, 1998], Brenner [*Trends in Genetics* **15**:132-133, 1999] and Bork [Bork *et al.*, *Trends in Genetics* **12**:425-427, 1996]" (the Examiner's Answer at page 9). As Appellants have repeatedly detailed the shortcomings of each of these references, and reiterated these shortcomings in the Appeal Brief, Appellants will not address the shortcomings of each of these references again in the Reply Brief. However, Appellants respectfully point out that this position **directly** contradicts the position of the **USPTO itself**, which clearly "recognizes the assignment of function based on homology". Example 10 of the Revised Interim Utility Guidelines Training Materials (see **Exhibit B** of the Appeal Brief) only requires a similarity score greater than 95% to establish functional homology, without **any** direct demonstration of function. Thus, the USPTO itself clearly acknowledges that function can be established **only** on the basis of homology. Thus, scientific publications that generally assert that very small changes between amino acid sequences can lead to changes in function, or publications describing specific

examples of proteins, distinct from Appellants sequence, where a minor change in amino acid sequence has lead to a change in function, such as Doerks, Brenner, and Bork, have been viewed by the USPTO itself as **irrelevant** to the question of utility, and thus do not support the Examiner's allegation that the presently claimed sequence lacks utility.

The Examiner once again states that "(s)ince the AY029200 polynucleotide is a post-filing reference, the asserted utility was not well-established at the time of filing" (the Examiner's Answer at page 10). Appellants reiterate that this argument is **completely** irrelevant to the **utility** issue at question here. Appellants pointed out in the Appeal Brief that the utility of the presently claimed sequence as an ion channel protein was clearly asserted in the specification as originally filed, which is **all** that is required under 35 U.S.C. § 101. That others later confirm Appellants asserted utility to be true does not mean that the utility as originally asserted does not meet the requirements of 35 U.S.C. § 101.

Furthermore, Appellants detailed additional examples of the utility of the present nucleotide sequences, such as in assessing gene expression patterns using high-throughput DNA chips. The Examiner continues to question these assertions of utility, because "this is a utility that would apply to virtually ever (*sic*) member of a general class of materials, such as any collection of DNA" (the Examiner's Answer at page 13). Appellants wish to emphasize that the Examiner is once again clearly confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard (*Carl Zeiss, supra*). The "general class" to which the Examiner refers is **all** nucleic acids. Appellants reiterate that **not all nucleic acids are expressed**, and therefore able to be used to monitor gene **expression** patterns using DNA chips. Appellants pointed out in the Appeal Brief that only a minor percentage (2-4%) of the genome actually encodes exons, which in-turn encode amino acid sequences. Once again, the Examiner is attempting to **narrowly** define the "general class" of the invention to include **only** those members that share the asserted utility, in this case being expressed, and then state that the asserted utility is "applicable to the general class of nucleic acids". Appellants respectfully point out that the "general class of nucleic acids" **cannot** be redefined to include **only** those nucleic acids that are expressed, as the Examiner is forced to do in order to support the allegation that the claimed nucleic acids lack a patentable utility. Therefore the present claims

are clearly in compliance with 35 U.S.C. § 101.

As yet a further example of the utility of the presently claimed polynucleotide, Appellants noted in the Appeal Brief that the present nucleotide sequence has a specific utility in "identification of coding sequence" (specification at page 2, lines 34-36) and in "determining the genomic structure" of the protein encoding regions of the corresponding human chromosome (specification at page 10, line 32). The Examiner states that "Appellant newly cites the Venter reference [Venter *et al.*, *Science* **291**:1304, 2001] to allegedly demonstrate the significance of expressed sequence information in the structural analysis of genomic data" (the Examiner's Answer at page 14). Appellants respectfully point out for the record that the "Venter reference" is **hardly** "newly cited", having been cited by Appellants in this exact context in both the response filed on March 12, 2003 to the First Office Action in this case, which was mailed on December 13, 2002, and the response filed on August 28, 2003 to the Final Office Action in this case, which was mailed on May 30, 2003. Thus, the Examiner's allegation is **completely** without merit.

Appellants noted in the Appeal Brief that regarding the utility requirements under 35 U.S.C. § 101, the Federal Circuit has clearly stated "(t)he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip Inc. v. Orange Bang Inc.*, 185 F.3d 1364, 51 USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that "(t)o violate § 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); "*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35 U.S.C. § 101". *Cross* at 748, emphasis added. Indeed, the Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable (*State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond vs. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (U.S., 1980)). Thus, based on the relevant case law, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner seems to discount the case law cited by Appellants, stating "(t)he claimed invention

in the instant case is drawn to nucleic acid sequences, not a device" (the Examiner's Answer at page 15). Appellants respectfully point out that the holding in these cases is **mandatory legal authority**, and that the Examiner **must** follow the precedent as applied to the broad issue at hand in each cited case, unless a case is specifically limited to it's facts by the **Court itself**. Furthermore, Section 101 of the Patent Act of 1952, 35 U.S.C. § 101, provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. Appellants point out that 35 U.S.C. § 101 covers devices (machines) as well as compositions, and makes no distinction between the two with regard to meeting the burden of complying with 35 U.S.C. § 101. Additionally, *Juicy Whip Inc. v. Orange Bang Inc.* cites *Brenner v. Manson*, 383 U.S. 519 (1966), which the Examiner **obviously** believes is relevant to the present case, since the Examiner **himself** cites this exact case **five times** in the Examiner's Answer (the Examiner's Answer at pages 4, 5, 8, 14, and 16). Thus, this argument is completely improper, and totally fails to support the alleged lack of utility of the presently claimed compositions.

For each of the foregoing reasons, as well as the reasons set forth in the Appeal Brief, Appellants submit that the rejection of claims 1 and 5-9 under 35 U.S.C. § 101 must be overruled.

B. Are Claims 1 and 5-9 Unusable Due to a Lack of Patentable Utility?

Regarding the rejection of claims 1 and 5-9 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by either a clear asserted utility or a well-established utility, Appellants submit that as claims 1 and 5-9 have been shown to have "a specific, substantial, and credible utility", as detailed in Section X(A) above, as well as Section VIII(A) of the Appeal Brief, the present rejection of claims 1 and 5-9 under 35 U.S.C. § 112, first paragraph, cannot stand.

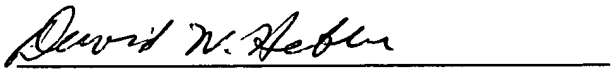
Appellants therefore submit that the rejection of claims 1 and 5-9 under 35 U.S.C. § 112, first paragraph, must be overruled.

XI. CONCLUSION

Appellants respectfully submit that, in light of the foregoing arguments, the Final Action's conclusion that claims 1 and 5-9 lack a patentable utility and are unusable by the skilled artisan due to a lack of patentable utility is unwarranted. It is therefore requested that the Board overturn the Final Action's rejections.

Respectfully submitted,

May 4, 2004
Date



David W. Hibler Reg. No. 41,071
Agent For Appellants

LEXICON GENETICS INCORPORATED
8800 Technology Forest Place
The Woodlands, TX 77381
(281) 863-3399

Customer # 24231

TABLE OF AUTHORITIES

CASES

STATUTES

123

05-05-04 FFW AF/1646

PTO/SB/21 (01-03)
Approval for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/918,359
Filing Date	Jul 30, 2001
First Named Inventor	Turner, Jr., C. Alexander
Art Unit	1646
Examiner Name	J. Murphy
Total Number of Pages in This Submission: 20	Attorney Docket Number: LEX-0208-USA

ENCLOSURES *(check all that apply)*

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to Group ***(Appeal Notice, Brief, Reply Brief)***
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below):*
  - Return Postcard

Remarks

Customer # 24231

EVERYTHING FILED IN TRIPLICATE

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Lexicon Genetics Incorporated Lance K. Ishimoto Reg. No. 41,866
Signature	Lance K. Ishimoto by David W. Huber DAVID W. HUBER REG. NO. 41,071
Date	May 4, 2004

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as Express mail Label #EL 982335855 US in an envelope addressed to:

Mail Stop: Appeal Brief - Patents, USPTO, PO Box 1450, Alexandria, VA 22313-1450 on this date: May 4, 2004

Typed or printed	Michelle Klein		
Signature	Michelle Klein	Date	May 4, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents. Washington, DC 20231.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.